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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,449	12/20/2001	Monica G. Marcu	213373	4132
23460	7590	08/23/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,449	MARCU ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

Reassignment Affecting Application Location

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

Status of Claims

2. Claims 1-17 and 22 are pending and currently under examination.

Status of Objection(s) and/or Rejection(s)

3. Applicant's May 14, 2004 submission with arguments directed to the 102 rejections set forth in the previous office action was found persuasive, hence, the Examiner withdraws the 102 rejections. In view of the withdrawal of the 102 rejections, claims 16-17 are found not to be enabling for the reason(s) set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-6, 8-15 and 22 remains and claims 16-17 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for contacting chaperone protein Hsp90 with coumarin or a coumarin derivative so that the coumarin and coumarin derivative inhibits Hsp90 from binding a client protein, does not reasonably provide enablement for binding a coumarin or coumarin derivative with any other chaperone protein so as to inhibit the chaperone protein from binding a client protein. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to use the invention commensurate in the scope with these claims.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In Applicant's May 14, 2004 submission, Applicant states that the Office alleges that the specification only teaches the claimed method wherein the chaperone protein is Hsp90, thus, the specification does not enable one of ordinary skill in the art to make and/or use the present invention to inhibit the binding of any other chaperone protein

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with its client protein. Applicant continues by pointing to the previous office action, the specification, as well as Jolly et al. to provide additional disclosure for a variety of different proteins that act as molecular chaperone. Specifically, Applicant points to the assays conducted by Applicant, pointing to Examples 1-4, and assert that those cited examples teach the skilled artisan how to make and use the claimed invention to the full scope of the claimed invention. Applicant concludes that sufficient teaching for one skilled in the art to identify other chaperone proteins that are inhibited by client protein interactions post contact with a coumarin or a coumarin derivative. Applicant further concludes that the skilled artisan would know how to conduct the assays with each candidate chaperone protein and that such assays constitute as routine screening for the skilled artisan, pointing to a statement made by the Federal Circuit, "[e]nablement is not precluded by the necessity for some experimentation such as routine screening." In re Wands.

Applicant's submission has been fully considered and is not found persuasive. Applicant's submission did not address the issue at hand as it pertains to the instant enablement rejection. The rejection is made on the basis that the skilled artisan would not be able to use the full scope of the instantly claimed invention without an undue burden of experimentation because of the limited teaching that is provided in the specification in combination with the state of the art. As noted in the previous office action, the specification only teaches Hsp90 as the only chaperone protein that is identified in the instant application as binding coumarin or a coumarin derivative so as to inhibit binding of the chaperone to a client protein. There is no teaching of other chaperone proteins that has been inhibited from binding to its client protein after contact

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with coumarin or coumarin derivative. Specifically, the specification does not teach inhibition of binding between a chaperone protein and a Hepatitis B virus reverse transcriptase, which Applicant has noted as a client protein, wherein the chaperone protein has been in contact with coumarin or a coumarin derivative.

Additionally, the claimed invention requires that the claimed method inhibit the binding of a chaperone protein with a hepatitis B virus reverse transcriptase, a client protein, whereupon the hepatitis B virus is inhibited. Applicant has not demonstrated that such client protein, including the inhibition of hepatitis B virus, can be inhibited by the claimed method. Moreover, Applicant has not provided any guidance that would direct the skilled artisan to identify the chaperone protein that is responsible for mediation of the correct assembly of hepatitis B virus reverse transcriptase, the client protein, whereupon the hepatitis B virus is inhibited.

Furthermore, the specification does not contain any guidance as to how to identify others that would have the required properties, i.e. wherein the binding of the chaperone protein to coumarin or a coumarin derivative would inhibit binding of the chaperone to a client protein. Such teaching is necessitated by the teaching that is rendered in a review article that is authored by Jolly et al., which summarizes the state of the art at or about the time the instantly claimed invention was made. Jolly et al. teaches that a variety of different heat shock proteins that act as molecular chaperones with different client proteins in many different organisms. Even those chaperones that are thought to have a role on oncogenesis are not disclosed as having structural features in common, and do not interact with the same array of client proteins. Additionally, while Applicant claims a method for inhibiting the binding of a chaperone

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protein with its client protein or client polypeptide comprising contacting a chaperone protein with coumarin or a coumarin derivative to inhibit the chaperone protein from binding its client protein or client polypeptide; Applicant has provided no evidence that the method will work for any other chaperone protein, thereby, inviting the skilled artisan to experiment and confirm what Applicant is claiming.

Therefore, in view of Applicant's arguments and the rejection set forth in the previous office action, both of which are summarized above, the instantly claimed invention remains rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for contacting chaperone protein Hsp90 with coumarin or a coumarin derivative so that the coumarin and coumarin derivative inhibits Hsp90 from binding a client protein, does not reasonably provide enablement for binding a coumarin or coumarin derivative with any other chaperone protein so as to inhibit the chaperone protein from binding a client protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in the scope with these claims without an undue burden of experimentation.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

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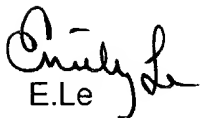
Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


E.Le


Shanon Foley
Patent Examiner, AU 1648